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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/419,611	10/18/1999	HIROSHI IZUI	0010-1045-0	1525

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EXAMINER	
FRONDA, CHRISTIAN L	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/419,611	IZUI ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 6-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 6-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 October 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/10/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 2, and 6-19 are under consideration in this Office Action. New rejections and new grounds for rejection are stated in the instant Office Action. The rejection under 35 USC 103 stated in the previous Office Action has been withdrawn.

Claim Rejections - 35 U.S.C. § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1, 2, and 6-19 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claims as written do not sufficiently distinguish over nucleic acids, proteins, cells, or antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "transformed microorganism" or "recombinant microorganism". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, and 6-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are genus claims that are directed toward any polynucleotide of any nucleotide sequence encoding any citrate synthase of any amino acid sequence "derived from" any coryneform bacterium.

Given the broadest interpretation for the phrase "derived from", the claim encompasses a highly variant genus of polynucleotides which encompass yet to be discovered polynucleotides encoding citrate synthase and polynucleotides which are not limited to polynucloetides having properties or characteristics (i.e. nucleotide sequence) unique to and obtainable from coryneform bacteria. The scope of the claim includes many polynucleotides with widely differing structural, chemical, and physical characteristics, and the genus is highly variable because a significant number of structural differences between genus members is permitted.

However, the specification only describes a polynucleotide isolated from *Brevibacterium lactofermentum* encoding a citrate synthase and a *Enterobacter agglomerans* and *Klebsiella planticola* transformed with said polynucleotide. The specification fails to provide a written description of additional representative polynucleotides as encompassed by the genus claims.

Regarding genus claims 11-19, the limitation that the DNA encoding a coryneform bacterium citrate synthase is isolated by amplification with primers does not meet the written description requirement since any DNA of any sequence including yet to be discovered polynucleotides which can be amplified and encode citrate synthase are not described by the specification. The only representative DNA encompassed by the highly variant genus is a polynucleotide isolated from *Brevibacterium lactofermentum* encoding a citrate synthase.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Amending the claims to recite the specific nucleotide sequence (SEQ ID NO:) of the polynucleotide isolated from *Brevibacterium lactofermentum* encoding a citrate synthase may overcome this rejection.

6. Claim 1, 2, and 6-19 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the

state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any polynucleotide of any nucleotide sequence encoding any citrate synthase of any amino acid sequence "derived from" any coryneform bacterium. Given the broadest interpretation for the phrase "derived from", the claim encompasses a highly variant polynucleotides which encompass yet to be discovered polynucleotides encoding citrate synthase and polynucleotides which are not limited to polynucloetides having properties or characteristics (i.e. nucleotide sequence) unique to and obtainable from coryneform bacteria.

The specification provides guidance for the polynucleotide encoding citrate synthase from *Brevibacterium lactofermentum*. However, the specification does not disclose the specific nucleotide sequence of the polynucleotide encoding citrate synthase from *Brevibacterium lactofermentum*.

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed invention is undue and outside the scope of routine experimentation since [one must search for and screen for any polynucleotide from any biological source, expressing the polynucleotide, and determining whether the expressed protein has citrate synthase activity. Teachings regarding how to search for and screen for the desired polynucleotide is not guidance on how to make the polynucleotide. The recitation of primers of SEQ ID NO: 1 and SEQ ID NO: 2 used to amplify the polynucleotide encoding citrate synthase does not meet the enablement requirement since any polynucleotide including yet to be discovered polynucleotides would have to been screened for and searched to find a polynucleotide encoding any citrate synthase. Furthermore, predictability in the art of success is extremely low since no information is provide by the specification regarding the specific identity and sequence/structure of any other polynucleotide encoding any citrate synthase.

Amending the claims to recite the specific nucleotide sequence (SEQ ID NO:) of the polynucleotide isolated from *Brevibacterium lactofermentum* encoding a citrate synthase may overcome this rejection.

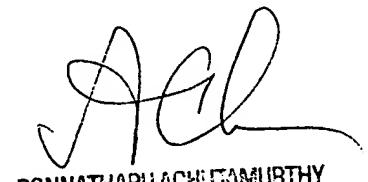
Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Christian L. Fronda whose telephone number is (571)272-0929. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571)272-0928. The offical fax phone number (703)872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571)272-1600.

CLF



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